UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/634,642	08/04/2003	William Suttle Peters	13634.4003	7193

34313 7590 08/18/2006

ORRICK, HERRINGTON & SUTCLIFFE, LLP
IP PROSECUTION DEPARTMENT
4 PARK PLAZA
SUITE 1600
IRVINE, CA 92614-2558

EXAMINER	
ALTER, ALYSSA M	

ART UNIT	PAPER NUMBER
3762	

DATE MAILED: 08/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/634,642	PETERS ET AL.	
	Examiner	Art Unit	
	Alyssa M. Alter	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 May 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17 and 19-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-17 and 19-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *04 August 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

Applicant's arguments filed May 23, 2006 have been fully considered but they are not persuasive. Furthermore, the amendment to the claims adds new matter, which is inconsistent with specification. However, claims 1-32 stand rejected under Dobak, III et al. (US 5,827,171) and Dobak, III et al. (US 5,820,542).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

1. Claims 1-19, 28-29 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The Applicant claims a "non-expandable shell" in line 4 of claim 1, however the Applicant only discloses on page 2, paragraph 27 "an inelastic, preferably plastic, shell". Therefore, the "non-expandable shell" was not reasonably described in the specification.

The claims are further rejected under 35 U.S.C. 112, first paragraph, for recitation of a negative limitation, which does not have basis in the original disclosure . (see MPEP 2173.05(i))

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claims 1-19, 23, 28-29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1, line 4 discloses a "non-expandable shell". The Applicant definition of "non-expandable" is unclear since the specification does not support such limitation.

As to claim 13, the claim recites, "that there is substantially no space between" the lumen and a balloon or chamber. This is a vague limitation and it is unclear how much space between the two components that the Applicant intends to encompass by reciting "substantially no space between".

As to claim 23, the claim states that the balloon or chamber expands away from the wall of the shell. However, it is unclear which wall the balloon or chamber is expanding towards and which wall the balloon or chamber is expanding away from.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

1. Claims 1-11, 13, 16-17, 23-26 and 28-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dobak, III et al. (US 5,827,171) in view of Bley et al. (US

5,674,241). Dobak, III et al. discloses the claimed invention except for the non-expandable stent or shell. Bley et al. teaches that it is well known in the art to have a number of different types of stents, both expandable and non-expandable as set forth in column 1, lines 20-38, for the purpose of stenting body passages. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the expandable stent as taught by Dobak, III et al. with the non-expandable stent as taught by Bley et al., in order to provide rigidity to a weakened body passage. Furthermore, since both expandable and non-expandable stents are well known in the art, it would have been obvious to modify the type of stent in the therapy system in order to modify the treatment to meet specific patient needs and requirements.

As to claim 1, it has been held that the recitation that an element is "adapted to" perform a function in not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. *In re Hutchison, 69 USPQ 138.*

Also, the functional language and introductory statement of intended use of claim 1 has been carefully considered but are not considered to impart any further structural limitations over the prior art. Since Dobak, III et al. utilizes a balloon and a shell as claimed by the Applicant, Dobak, III et al. is therefore capable of using the shell to provide location and direction to the balloon during inflation and deflation. In addition nothing prevents Dobak, III et al. from employing the shell for location and direction for a specific pattern of inflation and deflation. Therefore, the balloon is capable of being used with a shell to modify inflation and deflation.

As previously made of record, regarding to claims 1-2, 7-8 and 25, figure 1 depicts catheter 12 with the inner balloon 14 is the balloon or chamber and the outer balloon is a protective balloon 18, which acts as a shell. The stent 20 is disposed within balloon 16 and is an expandable frame. Thus it is balloon or chamber expandable.

As previously made of record, regarding to claims 3, 24 and 29, since the balloon 14 is located on the inside of the stent 20, the balloon is attached to the inner wall of the frame. Furthermore, since the balloon is disposed within the stent in the same system, the balloon and stent are necessarily coupled.

As previously made of record, regarding to claim 4, figure 3 displays a self-expanding stent 20.

As previously made of record, regarding to claims 5-6, "the stent 20 used in this embodiment (figure 2) is the thermally expanding stent 20 made of a material such as nitinol"(col. 7, lines 37-38). Nitinol is a nickel-titanium alloy, which is a shape memory alloy and is also a spring material.

As previously made of record, regarding to claim 9, "the stent 20 is an expandable, substantially cylindrical, lattice of elongated elements of plastic or metal. It can be similar to cardiovascular stents known in the art"(col. 5, lines 38-39). The examiner considers the lattice of elongated elements to be a lattice of wires.

As to claim 10, the Applicant argues on page 8 that "the stent of Dobak, III et al. cannot be covered with a fabric because the stent is buried in balloon 16".

As previously made of record, regarding to claim 10, "the balloons 14, 16, 18 are made of a flexible material which can expand up to a desired size, or diameter, after

which the material essentially does not expand further, even if the pressure inside the balloon is increased further. Such materials, and the processes used in their fabrication, are widely used in the manufacture of balloons for angioplasty"(col. 5, lines 16-22). Since the balloons cover the stents, the examiner considers the balloons to be comprised of a fabric and thus the stents are covered with a fabric.

Therefore, since the balloon 16 covers the stent, the examiner considers the balloon to be comprised of a fabric and thus the stents are covered with a fabric.

As previously made of record, regarding to claim 11, the balloon forms a coating around the stent.

As previously made of record, regarding to claim 13, since the balloon is located inside the lumen of the stent, the balloon extends around the full circumference of the frame lumen.

As previously made of record, regarding to claim 16-17, "when the outer balloon 16 is in the expanded state, a control space 26 is created between the outer balloon 16 and the inner balloon 14. This control space 26 is repetitively evacuated and pressurized with a control fluid, to achieve the expansion and collapse of the inner balloon 14"(col. 6, lines 31-35). As seen in figure 1 there is a control fluid pressure source P is connected to the balloon chamber(s) via the conducting tube (depicted as "A"). This control fluid affects the control space 26 to

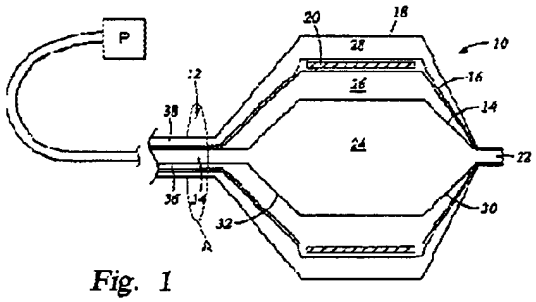

Fig. 1

facilitate a pumping action and as such the balloon or chamber (balloon 14) is connected to the control fluid pressure source.

As to claim 23, the Applicant discloses the balloon or chamber expands away from the wall of the shell. However, as explained above, the examiner is unsure which wall the balloon or chamber is expanding towards and which wall it is expanding away from. Therefore, in regards to the unclear recitation, the balloon of Dobak, III et al. expands towards part of the shell wall and expanding away from another part of the shell wall.

As to claim 26, there necessarily has to be an aperture in a artery wall in order to place the catheter delivery system into the vasculature.

As previously made of record, regarding to claim 28, the circulatory assist device has a port 22 for the flow of blood or other vascular fluid. Therefore, blood would flow through the balloon and stent instead of flowing over the surface of the shell or protective balloon 18. Furthermore, it has been held that the recitation that an element is "adapted to" perform a function in not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. *In re Hutchison, 69 USPQ 138.*

As to claim 30, the claim recites the limitation, a "shell having an arcuate cross-section, the interior surface of said balloon or chamber facing the concave surface of said shell". The shell, as seen in figure 1, has an interior concave surface and an arcuate cross-section.

2. Claims 1-17, 23-26 and 28-30 stand rejected and 31 is rejected under 35 U.S.C. 102(b) as being anticipated by Dobak, III et al. (US 5,820,542) in view of Bley et al. (US 5,674,241). Dobak, III et al. discloses the claimed invention except for the non-expandable stent or shell. Bley et al. teaches that it is well known in the art to have a number of different types of stents, both expandable and non-expandable as set forth in column 1, lines 20-38, for the purpose of stenting body passages. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the expandable stent as taught by Dobak, III et al. with the non-expandable stent as taught by Bley et al., in order to provide rigidity to a weakened body passage. Furthermore, since both expandable and non-expandable stents are well known in the art, it would have been obvious to modify the type of stent in the therapy system in order to modify the treatment to meet specific patient needs and requirements.

As to claim 1, it has been held that the recitation that an element is "adapted to" perform a function in not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. *In re Hutchison, 69 USPQ 138.*

Also, the functional language and introductory statement of intended use of claim 1 has been carefully considered but are not considered to impart any further structural limitations over the prior art. Since Dobak, III et al. utilizes a balloon and a shell as claimed by the Applicant, Dobak, III et al. is therefore capable of using the shell to provide location and direction to the balloon during inflation and deflation. In addition nothing prevents Dobak, III et al. from employing the shell for location and direction for a

specific pattern of inflation and deflation. Therefore, the balloon is capable of being used with a shell to modify inflation and deflation.

As previously made of record, regarding to claims 1-2, 7-8 and 25, figure 1 depicts catheter 12 with a pumping membrane 14 as the balloon or chamber and the protective membrane 18, which acts as a shell. The stent 20 is disposed within housing 16 and is an expandable frame. Thus it is balloon or chamber expandable.

As previously made of record, regarding to claims 3, 24 and 29, since the pumping membrane or balloon 14 is located on the inside of the stent 20, the balloon is attached to the inner wall of the frame. Furthermore, since the balloon is disposed within the stent in the same system, the balloon and stent are necessarily coupled.

As previously made of record, regarding to claim 4, figure 3 displays a self-expanding stent 20.

As previously made of record, regarding to claims 5-6, "the stent 20 used in this embodiment is the thermally expanding stent 20 made of a material such as nitinol"(col. 9, lines 18-19). Nitinol is a nickel-titanium alloy, which is a shape memory alloy and is also a spring material.

As previously made of record, regarding to claim 9, "the stent 20 is an expandable, substantially cylindrical, lattice of elongated elements of plastic or metal. It can be similar to cardiovascular stents known in the art"(col. 7, lines 19-21). The examiner considers the lattice of elongated elements to be a lattice of wires.

As to claim 10, the Applicant argues on page 8 that "the stent of Dobak, III et al. cannot be covered with a fabric because the stent is buried in housing 16".

As previously made of record, regarding to claim 10, "the housing 16 and the membranes 14,18 can be made of a flexible material which can expand up to a desired size, or diameter, after which the material essentially does not expand further, even if the pressure inside the housing or membranes is increased further. Such materials, and the processes used in their fabrication, are widely used in the manufacture of balloons for angioplasty"(col. 6-7, lines 64-67 and 1-3). Since the housing could consist of two laminated membranes with the stent disposed within them and the examiner considers the membranes to be comprised of a fabric, the stent as a result would be covered with a fabric.

Therefore, since the member 16 covers the stent, the examiner considers the balloon to be comprised of a fabric and thus the stents are covered with a fabric.

As previously made of record, regarding to claim 11, the balloon forms a coating around the stent.

As previously made of record, regarding to claim 13, since the balloon is located inside the lumen of the stent, the balloon extends around the full circumference of the frame lumen.

As previously made of record, regarding to claim 16-17, "when the housing 16 is in the expanded state, a control chamber 26 is created between the housing 16 and the pumping membrane 14. This control chamber 26 is repetitively evacuated and pressurized with a control fluid, to achieve the expansion and collapse of the pumping membrane 14"(col. 8, lines 12-17). As seen in figure 1 there is a control fluid pressure source P is connected to the balloon chamber(s) via the conducting tube (depicted as

"A"). This control fluid affects the control chamber 26 to facilitate a pumping action and as such the pumping membrane 14 is connected to the control fluid pressure source.

As to claim 23, the Applicant discloses the balloon or chamber expands away from the wall of the shell. However, as explained above, the examiner is unsure which wall the balloon or chamber is expanding towards and which wall it is expanding away from. Therefore, in regards to the unclear recitation, the balloon of Dobak, III et al. expands towards part of the shell wall and expanding away from another part of the shell wall.

As to claim 26, there necessarily has to be an aperture in an artery wall in order to place the catheter delivery system into the vasculature.

As previously made of record, regarding to claim 28, the circulatory assist device has a port 22 for the flow of blood or other vascular fluid. Therefore, blood would flow through the balloon and stent instead of flowing over the surface of the shell or protective balloon 18. Furthermore, it has been held that the recitation that an element is "adapted to" perform a function in not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. *In re Hutchison, 69 USPQ 138.*

As to claim 30, the claim recites the limitation, a "shell having an arcuate cross-section, the interior surface of said balloon or chamber facing the concave surface of said shell". The shell, as seen in figure 1, has an interior concave surface and an arcuate cross-section.

3. Claims 21-22 and 27 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Dobak, III et al. (US 5,827,171) or Dobak, III et al. (US 5,820,542) for reasons previously made of record and stated below.

As to claims 21-22 and 27, the Applicant argued that "it would be impossible to place the stent intraluminally and then connect it to a fluid pressure source....because the pressure source of Dobak, III et al. must be intralumnial." The examiner cannot locate where Dobak, III et al. discloses that the fluid pressure source is intraluminal. On the contrary, Dobak, III discloses that a control fluid device or pump P could alternatively be a syringe in US 5,820,542, col. 8, lines 57-61 and US 5,827,171, col. 7, lines 9-13. In order for a syringe to be utilized as a fluid pressure device, it would exist external to the body. Therefore the system, as disclosed by Dobak, III et al., is a transdermal or hybrid system that is not completely intraluminal as the Applicant claims. Therefore, claims 21-22 and 27 stand rejected.

As previously made of record:

As to claims 21 and 27, Dobak, III et al. discloses the claimed invention except for the sternotomy. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the placement of the assist device as taught by Dobak, III et al. with implantation by a sternotomy since it was known in the art that to implant medical devices into the patients chest cavity via a sternotomy. Furthermore, it is also well know in the art to modify a surgical procedure to meet specific patient needs.

As to claim 22, Dobak, III et al. discloses the claimed invention except for the aortotomy. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the placement of the assist device as taught by Dobak, III et al. with connecting the device via a aortotomy since it was known in the art to implant s known to insert a balloon into the thoracic aorta to augment blood flow, as taught by Dobak, III et al. '542. Furthermore, it is also well know in the art to modify a surgical procedure to meet specific patient needs.

4. Claims 19-20 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Dobak, III et al. (US 5,827,171) or Dobak, III et al. (US 5,820,542) in view of Lederman (US 6,210,318) as previously made of record and stated below. Since Dobak, III et al., teaches a transdermal or hybrid system (as explained above) that is not completely intraluminal as the Applicant claims, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the fluid as taught by Dobak, III et al. with a gas as taught by Lederman, since both fluids facilitate the inflation and deflation of the pumping balloon.

5. Claims 13-14 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dobak, III et al. (US 5,827,171) or Dobak, III et al. (US 5,820,542). Dobak, III et al. discloses the claimed invention but does not disclose expressly the balloon or chamber extending around only a portion of the circumference, instead of the entire circumference. It would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the expansion of the balloon or chamber to the full

circumference as taught by Dobak, III et al., with the expansion to a partial circumference, because Applicant has not disclosed that the expansion to a partial circumference provides an advantage, is used for a particular purpose, or solve a stated problem. One of ordinary skill in the art, furthermore, would have expected the Applicant's invention to perform equally well with the expansion to the full circumference as taught by Dobak, III et al., since both the full and partial circumference expansion would both equally assist the heart as a pumping circulatory assist device.

Therefore, it would have been an obvious matter of design choice to modify the expansion of the balloon or chamber to obtain the invention as specified in the claim(s).

Specification

1. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: "non-expandable" as recited in claim 1, as well as, "concave" and "arcuate cross-section" as recited in claim 30.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alyssa M. Alter whose telephone number is (571) 272-4939. The examiner can normally be reached on M-F 9am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

GEORGE R. EVANISKO
PRIMARY EXAMINER
5/17/6

Alyssa M Alter
Examiner
Art Unit 3762